

REMARKS

New Claims 24-35 correspond to previously cancelled Claims 1-7, 18-21, and 23. Claims 9-16 and new Claims 24-35 are pending.

35 USC 103(a) REJECTION

The Examiner rejected Claims 9-16 under 35 USC §103(a) as obvious over US 5,984,102 (Tay). Claim 9 describes an electrode system comprising a pair of electrodes disposed on opposite sides of a rigid non-conductive release liner from which the electrodes may be peeled and removed, wherein each electrode comprises an electrode body having first and second sides, wherein the first side comprises a flexible, nonconductive moisture barrier layer having a sealable periphery and the second side comprises a conductive layer, and an electrically conductive gel layer interposed between the conductive layer and the rigid non-conductive release liner in a vapor, air, and/or moisture-proof enclosure formed by the sealing of the periphery of the moisture barrier layer of each electrode to the release liner to enclose the gel layer of each electrode in a moisture barrier enclosure on its respective side of the rigid release liner. Independent Claim 10 describes the Claim 9 invention, wherein the electrodes are further in electrical contact with each other through a conductive path that is disposed within the non-conductive release liner and which is in electrical contact with both electrodes through said gel layers.

Tay teaches a sealed package system for housing a pair of electrodes inside a flexible envelope arranged to

form an interior cavity. A flexible, optionally conductive, liner is disposed between each of the electrodes inside the package.

The Examiner contends that Tay discloses the Claims 9 and 10 inventions except for the rigid non-conductive release liner. The Examiner further contends that substituting rigid for the flexible Tay release liner is a matter of obvious design choice. Applicant respectfully traverses Examiner's rejection.

First, Tay fails to disclose or suggest any sealing of an electrode body to a rigid release liner, as described by Claim 9. Tay instead discloses a sealing envelope formed by two package layers 142, 143 which are sealed together about their periphery. Applicant respectfully points out that the package layers form no part of electrodes 128, 129. Fig. 14 and Col. 6 ln. 5-12. The Tay electrode base layers 130, 133 are furthermore not sealed to anything; they merely overlay respective gel layers 131, 134.

Furthermore, Tay mentions nothing about a release liner that must be rigid. On the contrary, an inspection of Fig. 14 indicates that the release liner/separator layer 136 is the same thickness as electrode base layers 130, 133, which are elsewhere described only as a "thin, flexible, polymeric substance". Col. 2 ln. 66-67. Nor does Tay suggest that the separator layer 136 would have any different rigidity than the base layers. Thus, Tay teaches away from the Claim 9 limitation.

Tay also fails to disclose or suggest any electrode body for sealing to the release liner which creates a moisture barrier enclosure for the gel layer. Instead, the only Tay element which has moisture barrier properties is

the package structure 12 in which the electrode is stored. Col. 3 ln. 57-60. All embodiments of the Tay electrode body 14/33/48/67/101/117/130/133, in contrast, must only be "non-conductive", "insulative", and "structural." Col. 2 ln. 63 - Col. 3 ln 4. Tay's failure to suggest a moisture barrier electrode body arises from Tay's failure to recognize the problem of obtaining long electrode shelf life without the need for a pouch-like package. Tay's non-recognition is a secondary factor for non-obviousness, because by not recognizing the problem, there is no incentive to one of ordinary skill in the art to develop the Claims 9 and 10 solution.

Similarly, Tay fails to solve previously unrecognized problems solved by the Claims 9 and 10 rigid release liner to which electrodes are sealed to each side to form a moisture barrier enclosure, such as:

- Faster cardiac rescue by eliminating steps required to unpack and discard electrode packaging, Appl. Pg.3 ln.25-28
- Eliminating extraneous packaging which after tearing open may adhere to the electrodes and interfere with the rescue, Appl. Pg.3 ln.5-7
- Easier peeling of flexible electrodes from the rigid release liner material, Appl. Pg.9 ln.7-15, and
- reducing the seal-bond-weakening effects caused by flexing of a flexible package. Appl. Pg.3 ln.2-5.

By failing to recognize any of the problems solved by the Claims 9 and 10 inventions or any solution to those

problems, Tay fails to overcome these additional secondary reasons for non-obviousness.

The Examiner rejected Claim 11 as obvious over Tay. Claim 11 describes the Claim 9 invention, wherein each electrode further comprises a lead wire that is connected through said first side to said second side of the electrode and which electrically connects the electrode to a medical device.

The Examiner, pointing to Fig. 13, contends that Tay discloses electrode lead wires 132, 135 that are connected through the first side to the second side of the electrode and which electrically connects the electrode to a medical device. Applicant respectfully traverses Examiner's argument.

Tay fails to disclose any lead wire which connects through the first side to a second side of an electrode. Tay instead describes lead wires 132, 135 disposed on and remaining on a single side of the electrode and which pass out the peripheral edge of the electrode. Fig. 14. Nor would there be any incentive for one of ordinary skill in the art to modify Tay such that a lead wire passes through the electrode instead of out the periphery, because the Tay electrode bodies 130, 133 provide no moisture barrier around that periphery. Because there is no teaching, suggestion or motivation within Tay to so modify, Tay also fails to suggest the Claim 11 limitation.

For all of these reasons, Claims 9 and 10 are not anticipated or non-obvious, and are thus allowable over Tay. Claims 11-16 are similarly allowable by reason of their dependency on Claim 9.

In his October 30, 2009 Office Action, the Examiner finally rejected as anticipated by or obvious over Heath (US 4,419,998) the now-cancelled claims 1-3, 6, 7, 18-20, and 23, which correspond to new Claims 24-26, 29, 30, 31-33 and 35, respectively, under 35 USC §102(b) or 103(a).

Independent Claim 24 describes an electrode comprising an electrode body having a first and second side, wherein the first side comprises a flexible moisture barrier layer comprising a heat-sealable periphery with a peel tab extending therefrom and the second side comprises a conductive layer, an electrically conductive gel layer disposed on the electrode body and which is further in electrical communication with the conductive layer, the periphery of the heat-sealable moisture barrier layer extending beyond the periphery of the gel layer, and a rigid non-conductive release liner to which the flexible moisture barrier layer is heat-sealed around the periphery of said gel layer by a heat seal with the gel layer in contact with the release liner to form a vapor, air, and/or moisture-proof enclosure of the gel layer so that the electrode may be stored in a desiccation-retarding condition without the need for storing the electrode in a separate desiccation-retarding pouch or envelope.

Independent Claim 31 describes a self-storing electrode system comprising first and second electrode bodies each having a first and second side, wherein the first side comprises a flexible non-conductive moisture barrier layer having a heat-sealable periphery with a peel tab extending therefrom and the second side comprises a conductive layer with does not extend to the periphery of the moisture barrier layer, an electrically conductive gel

disposed on each of the electrode bodies which is in electrical communication with the conductive layer of each electrode, a rigid release liner sealed by a heat seal to the periphery of the flexible moisture barrier layer of each electrode body with the gel in contact with the release liner to enclose, protect and prevent desiccation of the gel layer of each electrode body without the need for a separate enclosure such as a pouch or envelope, and a lead wire electrically coupled to each electrode body by means of a path that does not disrupt the moisture integrity of the release liner seal.

Each of the Claim 24 and Claim 31 inventions provide superior desiccation retardation as compared to a cover which is merely adhesively applied over the gel layer, so much so that a tab is desired to peel the electrode from the rigid release liner.

The Heath patent describes an electrode system that can be connected to an ECG system, a stimulation system, and a defibrillator. A gel foam disk of the electrode is protected by a cover which is secured to the adhesive layer on a ring which holds the gel foam disk in place (col. 15, lines 9-19). Heath gives no consideration to heat-sealing; only to an adhesive seal. The adhesively-attached cover is so lightly held in place that it is simply "removed" from the Heath electrode without need of a tab, handle, or other means to securely grasp the cover to pull it off. A peel tab is not suggested by Heath because Heath does not contemplate peeling his electrode from the cover. It is simply removed from the electrode.

Furthermore, Heath's cover sits above the gel foam disk, leaving an air pocket above the gel. His cover appears to enlarge this air pocket by its concave shape,

much like the concave cover of a domed cake plate cover which sits above the cake. But in this case the concave shape enlarges the air space between the gel foam disk and the inside of the cover, increasing the possibility that the gel will dry out. By contrast, the gel layer of the electrode of Claims 24 and 31 is in contact with the release liner as stated on page 9, lines 22-31 of the specification, eliminating any air space between the gel and the release liner which could tend to dry out the gel.

In addition, Heath fails to disclose or suggest the lead wire of Claim 31 whose path does not disrupt the moisture integrity of the release liner seal. Heath instead discloses a lead wire 43 which passes through the adhesive layer 69 between foam ring 79 and foam base 67. Fig. 4. Thus, the Heath lead wire 43 disrupts the integrity of the adhesive bond and opens a path from the gel in disk 75 to the outside environment.

For the above reasons, Claims 24 and 31, and dependent Claims 25-26, 29, 30, 32-33 and 35 are not anticipated by or rendered obvious by Heath.

The Examiner finally rejected dependent Claims 27, 28, and 34 under 35 U.S.C. §103(a) by combining US Pat. 4,989,607 (Keusch) with Heath. Keusch discloses a specially-formulated hydrogel sheet which is stored in moisture-impermeable packet or envelope (col. 14, lines 35-39 and col. 13, lines 36-65) prior to use. Keusch adds none of the elements of the inventions of Claims 24 and 31 described above to render these claims unpatentable by a combination with Heath. To the contrary, the use of the standard foil envelope by Keusch shows the need for storing a Keusch electrode in a separate desiccation-retarding pouch or envelope, contrary to the language of Claims 24

and 31. Keusch recognizes that such pouches or envelopes are conventionally heat-sealed, but fails to recognize that heat-sealing could be applied to an electrode moisture barrier layer to provide a sealed enclosure without the need for a separate pouch or envelope. Accordingly it is respectfully submitted that Claims 24 and 31 and their dependent Claims 27, 28, and 34 are patentable over Heath and Keusch.

CONCLUSION

In view of the foregoing amendment and remarks, it is respectfully submitted that Claims 9-16 are patentable over Tay. Claims 24-26, 29, 30, 31-33 and 35 are patentable over Heath and Claims 27, 28, and 34 are patentable over Heath and Keusch. Accordingly it is respectfully requested that the rejection of these claims under 35 U.S.C. §102(b) and §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance.

Respectfully submitted,

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